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| EXAMINER | |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/879,480 | WHITTIER ET AL. | |
| | Examiner | Art Unit | |
| | Carla Myers | 1634 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *12 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *28,30-40,45,46,49 and 50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28, 30-40, 45, 46, 49 and 50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/12/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

1. This action is in response to the amendment filed July 12, 2007. Applicant's arguments have been fully considered but are not persuasive to overcome all grounds of rejection. All rejections not reiterated herein are hereby withdrawn. This action is made final.

2. Claims 28, 30-40, 45, 46, 49 and 50 are pending and have been examined herein.

### Priority

3. The subject matter of the present claims is entitled to priority only to the instant filing date of June 12, 2001. A claim as a whole is assigned an effective filing date rather than the subject matter within a claim being assigned individual effective filing dates. The priority applications do not disclose the general concept of a method of managing female bovine mammals comprising each of the steps of managing a plurality of female bovine mammals for a reproductive factor, inducing early puberty in said plurality of female bovine mammals, inseminating substantially all of the female bovine mammals with sex-sorted spermatozoa, producing offspring comprising substantially all female offspring and harvesting substantially all of said plurality of female bovine mammals.

**Response to Remarks:**

In the response, Applicants state that the present invention is entitled to priority to provisional application 60/211,093, filed June 12, 2000. The response cites phrases recited throughout pages 1, 2, 3, 4, and 7 of the '093 provisional application as providing support for the claimed invention. However, these individual teachings do not provide specific support for the combination of steps and elements recited in the present

claims. For example, the statement at page 2 of '093 that "Early puberty permits early insemination" does not provide support for the concept of a method of managing a plurality of female bovine mammals for a reproductive factor, inducing early puberty in said plurality of female bovine mammals, inseminating substantially all of the female bovine mammals with sex-sorted spermatozoa, producing offspring comprising substantially all female offspring and harvesting substantially all of said plurality of female bovine mammals. The response cites page 4, 3rd full paragraph as providing support for the claimed invention. However, the cited text teaches that "Puberty was reached at various ages dependent on the individual heifer. One month prior to synchronization, 20% of the EW heifers were pubertal compared to 8% of the TW heifers. This induction of early puberty contributed to nutrition allowing greater gain and weight of the EW heifers." However, this disclosure does not provide support for the concept of a method wherein a plurality of female bovine mammals are managed for a reproductive factor, early puberty is induced in substantially all of said plurality of female bovine mammals, substantially all of the female bovine mammals are inseminated with sex-sorted spermatozoa, offspring are produced from substantially all female offspring and substantially all of said plurality of female bovine mammals are then harvested. Page 5 of '093 concludes that "Phase I of the integration of early weaning, sexed semen and single-calf heifer systems achieved increased BCS of dams; accomplished satisfactory gain performance of heifers which enabled induction of early puberty and resulted in 9 mo old heifers impregnated to sexed semen. Page 8 of '093 is also cited as teaching that "Phase I of the IS increased BCS of dams, enabled

greater gains and weights of heifers, induced early puberty and resulted in 9 mo old heifers pregnant to sexed semen." However, this disclosure of Phase I does not provide basis for the concept set forth in the claims wherein early puberty is induced in substantially all female bovine, at least one egg of substantially all early-puberty induced bovine are fertilized with sex-sorted semen, off-spring are produced by substantially all the fertilized bovine, and then substantially all of the female bovine are harvested after producing offspring. In conclusion, the individual disclosures cited throughout the '093 application do not provide support for the particular combination of steps and elements required by the present claims wherein the method requires each of the steps of managing a plurality of female bovine mammals for a reproductive factor, inducing early puberty in substantially all of said plurality of female bovine mammals, inseminating substantially all of the female bovine mammals with sex-sorted spermatozoa, producing offspring from substantially all female offspring, wherein the offspring comprise substantially all female offspring, and harvesting substantially all of said plurality of female bovine mammals after the step of producing offspring. **Claim**

**Rejections - 35 USC § 112**

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 28, 30-40, 45, 46, 49 and 50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 28, 30-40, 45, 46, 49 and 50 are indefinite over the recitation of "managing said plurality of bovine female mammals for at least one reproductive factor." It is unclear as to what is intended to be meant by managing an animal for a reproductive factor. It is also unclear as to how this step is intended to be related to the remainder of the recited steps because the claims because the claims do not set forth how the female bovine are managed based on the reproductive factor and do not state the relationship between the reproductive factor and the remaining steps of inducing early puberty, fertilizing an egg, producing offspring and harvesting the female bovine.

**Response to Remarks:**

In the response, Applicants state the concepts related to reproductive management of animals is known in the art and is evidence by the teachings of Pursel, Bagnato, Pankowski, Scipioni and Fricke. This argument is not persuasive because Applicants do not point to any particular teachings in these references which define the phrase "managing said plurality of bovine female mammals for at least one reproductive factor," such that it would be clear that one of skill in the art at the time the invention was made would know what is intended to be meant by this phrase. While the cited references may teach methodologies for the reproduction of animals, the cited references do not appear to provide a clear definition for what is intended to be meant by managing an animal for a reproductive factor.

Applicants further assert that the remainder of the steps of the claim are concerned with reproduction of bovine and thereby the relationship between step a) and the remainder of the claim is clear. This argument is also not persuasive. The fact the

claim further recites steps related to reproduction does not clarify the relationship between the step of managing any reproductive factor and the specific steps of inducing early puberty, fertilizing an egg, producing offspring and harvesting bovine once they have produced offspring.

B. Claim 45 is indefinite over the recitation of "unsexed spermatozoa" because this phrase is not clearly defined in the specification and there is no art recognized definition for this phrase. It is also unclear as to what constitutes a "typical number of unsexed spermatozoa." While the specification refers to "typical number" of unsorted spermatazoa , the specification does not define what is intended to be encompassed by a "typical number of unsexed spermatozoa."

**Response to Remarks:**

In the response, Applicants state that the term "unsexed spermatozoa" is a well known term in the art, as evidence by the fact that the term is used in the cited publications of Ferre, Grant, Seidel, Garner, Tubman and Weigel. This argument is not persuasive. The rejection is not based on the premise that the term did not previously exist. The rejection is based on the fact that this term is not defined in the specification, nor is it defined in the cited references, and thereby one of skill in the art cannot determine what would constitute the number of spermatozoa relative to a typical number of unsexed spermatozoa.

The response states that the specification at page 10, lines 16-22 recites the language of "a number of spermatozoa from about 10% to about 50% relative to a typical number of unsexed spermatozoa." The response states that the specification

incorporates by reference 09/001,394 and that this patent application also recites the phrase. However, a recitation of a phrase in the specification does not provide a definition for the phrase. In fact, the specification states only: in the artificial insemination sample can be no more than 10 million, for example. A low number of spermatozoa from about 10% to about 50% relative to the typical number of spermatozoa in an artificial insemination sample may be used. In certain species of bovine mammals, such as beef cattle, the number of spermatozoa can be no more than 5 million, no more than 3 million, or can even be as low as no more than 500,000, no more than 250,000, and in some embodiments of the invention no more than between 100,000 to 150,000 spermatozoa. In certain embodiments of the invention, the spermatozoa can be frozen and subsequently thawed prior to use. The number of motile spermatozoa in a frozen-thawed sample of spermatozoa may be reduced. " However, these teachings provide only an example of what might be included by the number of sperm used for insemination. This disclosure does not provide a complete definition for the phrase "typical number of unsexed spermatozoa." Further, Applicants state that the specification incorporates by reference the WO 99/33956 patent application and states that this application provides a definition for "typical number of unsexed spermatozoa." However, essential subject matter may not be incorporated by reference to a non-US patent application.

**Claim Rejections - 35 USC § 103**

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 28, 31-40, 45, 46, 49 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ereth (Proceedings Western Section, American Society of Animal Science. June 2000. 51: 441-443).

Ereth (page 442) teaches a method of managing a plurality of female bovine mammals comprising obtaining a plurality of female bovine mammals, managing the female bovine for a reproductive factor (i.e., managing the female bovine for their ability to reproduce), inducing early puberty in the female bovine, fertilizing at least one egg wherein fertilization is performed by artificial insemination using sex-sorted sperm, and producing female offspring from said bovine female mammals prior to the typical age of puberty.

Ereth does not exemplify a method wherein, following producing offspring, the female bovine are harvested.

However, Ereth (page 441) teaches the concept of a "single-calf heifer system (SCH)" which is designed to allow a heifer to produce one calf prior to harvest. Ereth (page 441) states that "(i)ntegrating early weaning with the single-calf heifer system may generate profit by decreasing costs of herd dams and increasing value of cull heifers." The reference (page 441) also states that "(e)arly puberty permits early insemination and is the key to the IS allowing for shorter days on feed as well as avoidance of carcass maturity problems." Further, Ereth (page 442) teaches that "(i)ntegration of early weaning, sexed semen, and single-calf heifer systems has the potential to create extra revenue for a producer by increasing value of non-replacement heifers while simultaneously decreasing feed costs to herd dames. By accomplishing the previous, the IS has the potential to generate profit."

At page 443, Ereth teaches that "Phase I of the integration of early weaning, sexed semen and single-calf heifer systems achieved increased BCS of dams; accomplished satisfactory gain performance of heifers which enabled induction of early puberty and resulted in 9 mo old heifers impregnated to sexed semen." Ereth (page 4\43) concludes that "(e)xploration of the complete system including and extending beyond phase I will achieve a better analysis of the IS potential to increase value of cull heifers."

Accordingly, It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Ereth so as to have included the additional step of harvesting the female bovine following the production of offspring in order to have provided a complete system which integrated the induction of

early puberty, early weaning, use of sex-sorted sperm and the single heifer replacement system, thereby allowing for the analysis of the complete system and potentially providing the advantage of producing an integrated system with increased profits.

Regarding claim 31, Ereth teaches using 3 million frozen-thawed spermatozoa (see page 442, column 2).

Regarding claim 32, Ereth (abstract) teaches inducing early puberty by 9 months of age (i.e., prior to about 270 days after birth).

Regarding claim 33, Ereth (page 442) teaches that induction of early puberty was accomplished by feeding the female bovine a sufficient ration of feed to produce an average weight gain of about 1.25 kg/day (i.e., "about 1.3 kg/day to about 1.4 kg/day").

Regarding claim 34, Ereth (pages 441 and 442) teaches early weaning of offspring in order to perpetuate the integrated system.

Regarding claim 35, Ereth (page 42) teaches early weaning at about 110 days after birth.

Regarding claim 36, Ereth (page 442) teaches synchronization of heifers at 250 days after birth using a synchronization program that lasted 35 days, and in which AI was performed up to 72 hours following the last PGF-2alpha injection. It is stated that a 45 day breeding period allowed heifers 3 opportunities for AI. Accordingly, Ereth teaches artificial insemination and fertilization of at least one egg at about 285 to 316 days after birth.

Regarding claims 37 and 38, Ereth (page 442) teaches synchronizing estrous by dressing animal feed with 0.5 mg MGA for 14 days and injecting PGF-2alpha 19 days following the last MGA feeding.

Regarding claims 39 and 40, Ereth (page 441) teaches that the female bovine should be harvested following the production of offspring, at an age in which the female bovine are about 24 months of age.

Regarding claim 45, Ereth teaches using 3 million sex-sorted sperm, which is considered to be 50% of a typical artificial insemination dosage of 10 million sperm.

Regarding claim 46, the method of Ereth can be used to produce female offspring at a percentage of 70% female offspring, about 80% female offspring, or about 90% female offspring.

Regarding claim 49, Ereth teaches that the single-calf heifer system includes producing one calf prior to harvest and replacing the harvested female bovine.

Regarding claim 50, Ereth (page 441) teaches that the method is one in which a female bovine produces offspring in a single parturition.

**Response to Remarks:**

In the response, Applicants state that Ereth is not prior art to the claimed invention because the claimed invention is entitled to priority to provisional application '093, filed June 12, 2000. This argument is not persuasive for the reasons set forth in paragraph 3 above. It is maintained that the claimed invention is entitled to priority to June 12, 2001.

The response states that the Ereth reference was published on June 21, 2000 as evidence in "Exhibit C." The response further states that B.A. Ereth is the same person as Barbi A Riggs and given the common authorship with the present application, "Applicant anticipates being able to disqualify the Ereth reference using a Katz-type declaration."

This argument has been fully considered but is not persuasive. It is noted that the authorship of the Ereth et al reference is distinct from the present inventorship, and thereby this reference constitutes prior art to the present invention. Further, a 132 Katz-type declaration has not been filed, nor has evidence been filed to establish that Barbi A. Riggs is the same person as B.A. Ereth. However, this should not be construed as an invitation for providing additional declarations or affidavits. As further stated in the MPEP 716.01 regarding the timely submission of evidence:

A) Timeliness.
Evidence traversing rejections must be timely or seasonably filed to be entered and entitled to consideration. In re Rothermel, 276 F.2d 393, 125 USPQ 328 (CCPA 1960). Affidavits and declarations submitted under 37 CFR 1.132 and other evidence traversing rejections are considered timely if submitted:
(1) prior to a final rejection,
(2) before appeal in an application not having a final rejection, or
(3) after final rejection and submitted
(i) with a first reply after final rejection for the purpose of overcoming a new ground of rejection or requirement made in the final rejection, or
(ii) with a satisfactory showing under 37 CFR 1.116(b) or 37 CFR 1.195, or
(iii) under 37 CFR 1.129(a).

6. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ereth (Proceedings Western Section, American Society of Animal Science. June 2000. 51: 441-443) in view of Seidel (1997; cited in the IDS).

The teachings of Ereth are presented above. Ereth does not exemplify a method of using live, non-frozen sperm.

However, Seidel et al (page 1261-1262) teach a method which includes the steps of: a) producing a female bovine mammal; b) inseminating said female bovine mammal with a sample containing sorted sperm at a purity of about 90% for X sorted sperm; c) fertilizing at least one egg within the mammal; and d) producing an offspring mammal. Seidel teaches using 1-2.5 x $10^5$ sorted live sperm for each artificial insemination. Seidel also states that the use of low doses of frozen semen show considerable promise for commercial applications (see page 1262).

In view of the teachings of Seidel (1997), it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Ereth so as to have used live, non-frozen sperm in situations in which the sperm could be used immediately after sorting because this would have prevented any damage that may occur to the sperm during freezing and thawing, thereby improving the effectiveness of the artificial insemination method.

**Response to Remarks:**

In the response, Applicants traversed this rejection for the same reasons as stated above. Accordingly, the response to those arguments apply equally to the present grounds of rejection.

7. Claims 28, 32-37, 39, 40, 46, 49 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ereth (Journal of Animal Science. 2000. Vol. 78, supplement 2, page 114, abstract 73).

Ereth teaches a method of managing a plurality of female bovine mammals comprising obtaining a plurality of female bovine mammals, managing the female bovine for a reproductive factor (i.e., managing the female bovine for their ability to reproduce), inducing early puberty in the female bovine, fertilizing at least one egg wherein fertilization is performed by artificial insemination using sex-sorted sperm, and producing female offspring from said bovine female mammals prior to the typical age of puberty.

Ereth does not exemplify a method wherein, following producing offspring, the female bovine are harvested.

However, Ereth teaches the concept of a "single-calf heifer system (SCH)" which is designed to allow a heifer to produce one calf prior to harvest. Ereth also teaches that "Phase I of IS included early weaning, estrous synchronization and AI". It is stated that "Phase I of the IS increased BCS of dams, enabled greater gains and weights of heifers, induced early puberty and resulted in 9 mo old heifers pregnant to sexed semen."

Accordingly, It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Ereth so as to have included the additional step of harvesting the female bovine following the production of offspring in order to have provided a complete system which integrated the induction of early puberty, early weaning, use of sex-sorted sperm and the single heifer replacement system, thereby allowing for the analysis of the complete system and potentially providing the advantage of producing an integrated system with increased profits.

Regarding claim 32, Ereth (abstract) teaches inducing early puberty by 9 months of age (i.e., prior to about 270 days after birth).

Regarding claim 33, Ereth (page 442) teaches that induction of early puberty was accomplished by feeding the female bovine a sufficient ration of feed to produce an average weight gain of about 1.2 kg/day (i.e., "about 1.3 kg/day to about 1.4 kg/day").

Regarding claim 34, Ereth (pages 441 and 442) teaches early weaning of offspring in order to perpetuate the integrated system.

Regarding claim 35, Ereth (page 42) teaches early weaning at about 110 days after birth.

Regarding claim 36, Ereth teaches artificial insemination and fertilization of at least one egg at about 293 days after birth.

Regarding claims 37, Ereth teaches synchronizing estrous using a MGA/PGF protocol.

Regarding claims 39 and 40, Ereth (page 441) teaches that the female bovine should be harvested following the production of offspring, at an age in which the female bovine are about 24 months of age.

Regarding claim 46, the method of Ereth can be used to produce female offspring at a percentage of 70% female offspring, about 80% female offspring, or about 90% female offspring.

Regarding claim 49, Ereth teaches that the single-calf heifer system includes producing one calf prior to harvest and replacing the harvested female bovine.

Regarding claim 50, Ereth (page 441) teaches that the method is one in which a female bovine produces offspring in a single parturition.

**Response to Remarks:**

In the response, Applicants state that Ereth is not prior art to the claimed invention because the claimed invention is entitled to priority to provisional application '093, filed June 12, 2000. This argument is not persuasive for the reasons set forth in paragraph 3 above. It is maintained that the claimed invention is entitled to priority to June 12, 2001.

The response states that the Ereth reference was published on June 21, 2000 as evidence in "Exhibit D." The response further states that B.A. Ereth is the same person as Barbi A Riggs and given the common authorship with the present application, "Applicant anticipates being able to disqualify the Ereth reference using a Katz-type declaration."

This argument has been fully considered but is not persuasive. It is noted that the authorship of the Ereth et al reference is distinct from the present inventorship, and thereby this reference constitutes prior art to the present invention. Further, a 132 Katz-type declaration has not been filed, nor has evidence been filed to establish that Barbi A. Riggs is the same person as B.A. Ereth.

8. Claims 30 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ereth (Journal of Animal Science. 2000. Vol. 78, supplement 2, page 114, abstract 73). in view of Seidel (1997; cited in the IDS).

The teachings of Ereth (Journal of Animal Science) are presented above. Ereth does not exemplify a method of using no more than 3 million live, non-frozen sperm.

However, Seidel et al (page 1261-1262) teach a method which includes the steps of: a) producing a female bovine mammal; b) inseminating said female bovine mammal with a sample containing sorted sperm at a purity of about 90% for X sorted sperm; c) fertilizing at least one egg within the mammal; and d) producing an offspring mammal. Seidel teaches using 1-2.5 x $10^5$ sorted live sperm for each artificial insemination. Seidel also states that the use of low doses of frozen semen show considerable promise for commercial applications (see page 1262).

In view of the teachings of Seidel (1997), it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Ereth so as to have used live, non-frozen sperm in situations in which the sperm could be used immediately after sorting because this would have prevented any damage that may occur to the sperm during freezing and thawing, thereby improving the effectiveness of the artificial insemination method.

Regarding claim 45, the use of 1-2.5 x $10^5$ sorted live sperm is considered to be less than 50% of a typical artificial insemination dosage of 10 million sperm.

**Response to Remarks:**

In the response, Applicants traversed this rejection for the same reasons as stated in paragraph 7 above. Accordingly, the response to those arguments apply equally to the present grounds of rejection.

9. Claims 31 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ereth (Journal of Animal Science. 2000. Vol. 78, supplement 2, page 114, abstract 73). in view of Seidel (1995; abstract 513, 'Insemination of heifers with very low numbers of frozen spermatozoa,' cited in the IDS of 6/12/01).

The teachings of Ereth are presented above. Ereth does not exemplify a method of using no more than 3 or 5 million frozen, thawed sperm.

Seidel (1995) teaches the effective insemination of heifers with thawed frozen sperm. The reference teaches that no differences were observed when using 1-5 x $10^5$ versus 10 x $10^6$ sorted sperm.

In view of the teachings of Seidel (1995), it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Ereth so as to have used 1-5 x $10^5$ thawed-frozen sperm because this would have provided a convenient means for performing the insemination procedure in which the sperm could be sorted and stored prior to its use for artificial insemination.

Regarding claim 45, the use of 1-5 x $10^5$ sorted sperm is considered to be less than 50% of a typical artificial insemination dosage of 10 million sperm.

**Response to Remarks:**

In the response, Applicants traversed this rejection for the same reasons as stated in paragraph 7 above. Accordingly, the response to those arguments apply equally to the present grounds of rejection.

10. Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ereth (Journal of Animal Science. 2000. Vol. 78, supplement 2, page 114, abstract 73).

in view of Deutscher (cited in the IDS of 6/12/01).

The teachings of Ereth are presented above. Ereth states that the female bovine were synchronized using a MGA/PGF protocol, but does not specifically teach synchronizing estrous by dressing animal feed with 0.5 mg MGA for 14 days and injecting PGF at 19 days following the last MGA feeding.

However, Deutscher teaches synchronizing estrous by dressing animal feed with 0.5 mg MGA for 14 days and injecting PGF at 19 days following the last MGA feeding (see page 165). The reference teaches that this method of synchronizing heifers results in an increased pregnancy rate (see page 164).

In view of the teachings of Deutscher, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Ereth so as to have synchronized estrous by dressing animal feed with 0.5 mg MGA for 14 days and injecting PGF at 19 days following the last MGA feeding order to have achieved the advantage set forth by Deutchser of increasing the pregnancy rates and thereby providing an effective method for managing cows.

**Response to Remarks:**

In the response, Applicants traversed this rejection for the same reasons as stated in paragraph 7 above. Accordingly, the response to those arguments apply equally to the present grounds of rejection.

11. Claims 28, 32, 33, 39, 40, 46, 49 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hohenboken (Theriogenology. 1999. 52: 1421-1433; cited in

the IDS of 6/12/01) in view of Petit (1975; cited in the IDS of 6/12/01) and Hall (Journal of Animal Science. 1997. 1606-1611; cited in the IDS of 6/12/01).

Hohenboken teaches a method of managing a plurality of female bovine mammals comprising obtaining a plurality of female bovine mammals, managing the female bovine for a reproductive factor (i.e., managing the female bovine for their ability to reproduce), fertilizing at least one egg of said female bovine wherein fertilization is performed by artificial insemination using sex-sorted sperm, producing female offspring from said bovine female mammals, and harvesting said female bovine following the production of offspring (see abstract and pages 1426 and 1428). Hohenboken teaches that use of sex semen to produce only one heifer calf allows for only one parturition per female and that most cows would be slaughtered at a young age to produce consumer-acceptable beef without a maturity discount (page 1428). It is further stated that "(i)n a favorable marketing environment and under conditions allowing first parturition at a younger age, sexed semen would help to achieve profitable SSBH beef production" (see page 1428). Additionally, Hohenboken (page 1426) states that mating younger cows would have the additional advantage of reducing calving difficulty and increasing calf survival.

Hohenboken does not exemplify a method of inducing early puberty in order to allow for the fertilization of younger cows.

However, Petit teaches that heifers vary with respect to the start of their first estrus. It is stated that in beef heifers, providing an improved nutrition from birth onwards results in an early onset of estrus and an increase in weight gain (see page

158). Petit teaches that inducing early puberty to produce early-maturing heifers is a means for managing animals so as to enhance their reproductive efficiency.

Additionally, Hall teaches inducing early puberty in heifers by causing a rapid weight gain then a slow weight gain for heifers at ages 6.5 months to 12.5 months (see for example page 1607). Hall teaches that inducing puberty is a means for managing animals so as to enhance their reproductive efficiency.

In view of the teachings of Petit and Hall, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Hohenboken so as to have induced early puberty in the female bovines that were to be artificially inseminated in order to have achieved the advantage set forth by Hall of enhancing their reproductive efficiency and the advantages discussed by Hohenboken of reducing calving difficulty, increasing calf survival and providing female bovine that could be harvested at a younger age, thereby providing consumer-acceptable beef without a maturity discount and improving the effectiveness of the integrated system.

Regarding claim 32, Hohenboken does not teach inducing early puberty at about 270 days. However, Hall teaches inducing early puberty by about 9.5 months of age (i.e. about 270 days after birth). Accordingly, It would have been obvious to one of ordinary skill in the art at the time the invention was made induced early puberty at a time of about 270 days after birth, depending on the breed of heifer, in order to have provide the most effective integrated breeding system.

Regarding claim 33, the combined references do not specifically teach inducing early puberty by feeding the female bovine a sufficient ration of feed to produce an

average weight gain of about 1.2-1.4 kg/day. However, Petit teaches that an improved level of nutrition, and thereby weight gain, induces early puberty and Hall teaches that increased weight gain induces early puberty. Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have optimized the amount of food given to the female bovine in order to have produced the most effective average weight gain, including an average weight gain of about 1.2 –1.4 kg/day, in order to have achieved the advantage of inducing early puberty. As discussed in MPEP 2144.05(b), "(w)here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller,* 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

Regarding claims 39 and 40, Hohenboken teaches that the female bovine should be harvested following the production of offspring, at an age in which the female bovine are about 24 months of age.

Regarding claim 46, the method of Hohenboken can be used to produce female offspring at a percentage of 70% female offspring, about 80% female offspring, or about 90% female offspring.

Regarding claim 49, Hohenboken (page 1428) teaches that the single-calf heifer system includes producing one calf prior to harvest and replacing the harvested female bovine.

Regarding claim 50, Hohenboken (page 1428) teaches that the method is one in which a female bovine produces offspring in a single parturition.

**Response to Remarks:**

In the response, Applicants traversed this rejection by stating that Hohenboken does not exemplify a method in which biological efficiency is increased using sexed semen. It is argued that Hohenboken merely speculates that such a method can be performed by does not present empirical evidence of accomplishing a herd management program. This argument is not persuasive because there is no requirement for Hohenboken to exemplify or provide evidence of accomplishing the method disclosed therein in order to render the claimed invention as obvious. Hohenboken specifically teaches these art recognized steps and provides the motivation to perform each of these steps to accomplish the objective of improving the biological efficiency of managing bovine. No evidence has been provided by Applicants to indicate that the method of Hohenboken would not be successful. Applicants are reminded that obviousness does not require absolute predictability but only the reasonable expectation of success. See In re Merck and Company Inc., 800 F. 2d 1091, 231 USPQ 375 (Fed. Cir. 1986) and In re O'Farrell, 7 USPQ2d 1673 (Fed. Cir. 1988).

Applicants assert that the suggestion of Hohenboken that sperm sexing may find application in a herd management system falls short of actually achieving such sperm sexing in a herd management practice. Again, there is no requirement under 35 USC 103 that a cited reference exemplifies what is known in the art – i.e., inseminating bovine with sex-sorted sperm. Obviousness does not require actual performance of the suggestions in the disclosure. Applicants statement that "(a)t the time of Hohenboken, sperm sexing may have been a relatively new technology" is not supported by any factual evidence. It has not been established that the teachings of Hohenboken are not

sufficient to enable a general method of fertilizing at least one egg derived from a bovine using a plurality of sex-sorted spermatozoa.

Applicants state that Petit teaches only the general concept of inducing early puberty using improved levels of nutrition and improved feeding. It is argue that Hall teaches that the highest weight gain was 0.82 kg/d and the earliest onset of puberty was 9.5 months for 6 of 75 heifers. It is asserted that in contrast to the methods of Petit and Hall, "Applicants procedure" permitted a weight gain of 1.6 kg/day, induction of early puberty by 9 months and breeding by 10 months. These arguments have been fully considered but are not persuasive because Applicants appear to be arguing the unexpectedly improved results of a methodology that is not recited in the claims. The claims do not recite the particular feeding method disclosed in the specification for increasing the weight of bovine in order to achieve an increase in weight of 1.6 kg/day. Rather, the claims are inclusive of any type of method for inducing early puberty. The method of Petit and Hall achieves the objective of inducing early puberty and thereby meets the limitations of the claims. The response does not provide objective evidence that the method of Petit and Hall cannot be used in combination with the method of Hohenboken for producing offspring in bovine in which early puberty has been induced.

Applicants assert that because Hohenboken does not actually teach Applicant's invention and at best would merely make it obvious to try for Applicant's invention, the rejection should be withdrawn. This argument is not persuasive because the prior art when considered provides both the motivation and a reasonable expectation of success of combining the teachings of Hohenboken and Hall and Petit. As stated *in Ex parte*

*Kubin* (No. 2007-0819, Bd. Pat. App. & Int. May 31, 2007): "Under *KSR*, it is now apparent "obvious to try" may be an appropriate test in more situations than we previously contemplated. When there is motivation to solve a problem and there are a finite number of identified predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under 103. *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct 1727, 82 USPQ2d 1385, 1397 (2007)." This reasoning is also applicable to the present situation wherein the prior art of Hohenboken teaches a desire to improve the efficiency of bovine management by breeding bovine in which early puberty has been induced. Petit teaches that modification of the diet of bovine and particularly modification of the diet to improve weight gain and nutrition results in an early onset of estrus and an increase in weight gain (see page 158). Petit teaches that inducing early puberty to produce early-maturing heifers is a means for managing animals so as to enhance their reproductive efficiency. Further, Hall teaches that early puberty in heifers can be induced by causing a rapid weight gain then a slow weight gain for heifers at ages 6.5 months to 12.5 months (see for example page 1607). Hall also teaches that inducing puberty is a means for managing animals so as to enhance their reproductive efficiency. Thus, the ordinary artisan would have recognized that early puberty may be induced by modifying the diet of heifers with respect to the quantity and nutritional value of foods or by causing a rapid weight gain followed by a slow weight gain. It is considered to be well

within the skill of the art at the time the invention was made to select an appropriate feeding regimen for modifying the diet of bovine in order to induce early puberty. Applicant's arguments fail to establish that inducing early puberty according to the methods of Petit and Hall would have been unpredictable and beyond the skill of the ordinary artisan. If Applicant maintains that the ability to induce early puberty is unpredictable and that there are too many "possible choices" to allow for the successful induction of early puberty, then Applicants should reconcile why they are enabled for any method for inducing early puberty (as claimed) The present specification teaches only one means for inducing early puberty. In fact, the specification (page 13) teaches that heifers were "fed a high energy diet to promote rapid growth of approximately 1.6 kg/day to reach 65% of mature weight." However, the specification does not appear to teach the particular composition of the "high energy diet." Given Applicant's assertion of unpredictability and the absence of teachings in the specification providing additional guidance as to how to select an appropriate feeding regimen to induce early puberty, it would appear to be unclear as to whether the skilled artisan could practice the claimed invention to achieve the induction of early puberty in substantially all heifers in the absence of a clear disclosure of the particular diet given to the heifers to induce early puberty. It is contradictory for Applicants to assert that they have enabled (and thereby are entitled to claim) any method for inducing early puberty, while arguing the high level of unpredictability in the art and large number of critical parameters that must be analyzed to achieve the induction of early puberty in the absence of guidance in the

specification for achieving the induction of early puberty using any method other than that generically described on pages 13 and 19 of the specification.

12. Claims 30 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hohenboken in view of Petit and Hall, and further in view of Seidel (1997).

The teachings of Hohenboken, Petit and Hall are presented above. The combined references do not teach a method in which the quantity of sperm to be used for artificial insemination is no more than 3 million live, non-frozen sperm.

However, Seidel et al (page 1261-1262) teach a method which includes the steps of: a) producing a female bovine mammal; b) inseminating said female bovine mammal with a sample containing sorted sperm at a purity of about 90% for X sorted sperm; c) fertilizing at least one egg within the mammal; and d) producing an offspring mammal. Seidel teaches using 1-2.5 x $10^5$ sorted live sperm for each artificial insemination. Seidel also states that the use of low doses of frozen semen show considerable promise for commercial applications (see page 1262).

In view of the teachings of Seidel, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Hohenboken so as to have used live, non-frozen sperm in situations in which the sperm could be used immediately after sorting because this would have prevented any damage that may occur to the sperm during freezing and thawing, thereby improving the effectiveness of the artificial insemination method.

Regarding claim 45, the use of 1-2.5 x $10^5$ sorted live sperm is considered to be less than 50% of a typical artificial insemination dosage of 10 million sperm.

**Response to Remarks:**

In the response, Applicants traversed this rejection for the same reasons as stated in paragraph 11 above. Accordingly, the response to those arguments apply equally to the present grounds of rejection.

13. Claims 31 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hohenboken in view Petit and Hall, and further in view of Seidel (1995).

The teachings of Hohenboken, Petit and Hall are presented above. The combined references do not teach a method in which the quantity of sperm to be used for artificial insemination is no more than 3 or 5 million frozen, thawed sperm.

However, Seidel (1995) teaches the effective insemination of heifers with thawed frozen sperm. The reference teaches that no differences were observed when using 1-5 x $10^5$ versus 10 x $10^6$ sorted sperm.

In view of the teachings of Seidel (1995), it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Hohenboken so as to have used 1-5 x $10^5$ thawed-frozen sperm because this would have provided a convenient means for performing the insemination procedure in which the sperm could be sorted and stored prior to its use for artificial insemination.

Regarding claim 45, the use of 1-5 x $10^5$ sorted sperm is considered to be less than 50% of a typical artificial insemination dosage of 10 million sperm.

**Response to Remarks:**

In the response, Applicants traversed this rejection for the same reasons as stated in paragraph 11 above. Accordingly, the response to those arguments apply equally to the present grounds of rejection.

14. Claims 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hohenboken, Petit and Hall and further in view of Grimes (1991; cited in the IDS of 6/12/01).

The teachings of Hohenboken, Petit and Hall are presented above. The combined references do not teach do not teach early weaning of the female bovine.

However, Grimes (pages 468 and 471) teaches methods in which calves are weaned at 110 or 222 days. Grimes teaches that early weaned calves consumed less food and thereby provide an economic advantage. Grimes also teaches harvesting the animals prior to 24 months (Table 3). At pages 471, Grimes states: "Early weaning could be used in an integrated production system to expedite the finishing phase and to slaughter younger animals. It also could be used to accelerate development of females who are to be placed into the breeding herd, thus allowing these females to be bred younger."

In view of the teachings of Grimes, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have further modified the method of Hohenboken so as to have weaned the calves early, particularly after 110 days, in order to have provided the advantage set by Grimes of provide a more economical method for managing cows.

**Response to Remarks:**

In the response, Applicants traversed this rejection for the same reasons as stated in paragraph 11 above. Accordingly, the response to those arguments apply equally to the present grounds of rejection.

15. Claims 36, 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hohenboken, Petit and Hall and further in view of Deutscher (cited in the IDS of 6/12/01).

The teachings of Hohenboken, Petit and Hall are presented above. The combined references do not teach synchronizing estrus in the bovine prior to artificial insemination.

However, Deutscher teaches synchronizing estrous by dressing animal feed with 0.5 mg MGA for 14 days and injecting PGF at 19 days following the last MGA feeding (see page 165). The reference teaches that this method of synchronizing heifers results in an increased pregnancy rate (see page 164).

In view of the teachings of Deutscher, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Hohenboken so as to have synchronized estrous by dressing animal feed with 0.5 mg MGA for 14 days and injecting PGF at 19 days following the last MGA feeding order to have achieved the advantage set forth by Deutchser of increasing the pregnancy rates and thereby providing a more effective method for managing cows.

Regarding claim 36, modification of the method of Hohenboken so as to have induced early puberty at about 9 months and to have included the synchronization

method of Deutscher would have resulted in a method in which artificial insemination and fertilization of at least one egg occurred between about 283 to 316 days after birth.

**Response to Remarks:**

In the response, Applicants traversed this rejection for the same reasons as stated in paragraph 11 above. Accordingly, the response to those arguments apply equally to the present grounds of rejection.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is 571-272-0747. The examiner can normally be reached on Monday-Thursday (6:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carla Myers/

Primary Examiner, Art Unit 1634